

12 HOUR NASAL- oxymetazoline hcl spray
Healthlife of USA

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

12 Hour Nasal Spray
Nasal Decongestant

Drug Facts

Active Ingredient

Oxymetazoline HCL 0.05%

Purpose

Nasal Decongestant

Uses

Temporarily relieves nasal congestion due to:

- common cold
- hay fever
- upper respiratory allergies
- sinusitis
- shrinks swollen nasal membranes so you can breathe more freely

Warnings

Ask a doctor before use if you have

- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland

When using this product: do not use more than directed

- do not use for more than 3 days. use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen
- temporary discomfort such as burning, stinging, sneezing or an increase in nasal discharge may occur
- use of this container by more than one person may spread infection.

Stop use and ask a doctor

If symptoms persist.

If pregnant or breast feeding,

ask a health professional before use.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 6 to under 12 years of age (with adult supervision): 2 or 3 sprays in each nostril not more often than every 10 to 12 hours. Do not exceed 2 doses in any 24-hour period.
- children under six years of age: ask a doctor.
- To spray, squeeze bottle quickly and firmly. Do not tilt head backward while spraying. Wipe nozzle clean after use.

Other Information

- store between 20°C to 40°C (68°F to 104°F)
- retain carton for future reference on full labeling.

Inactive Ingredients

benzalkonium chloride solution, edetate disodium, polyethylene glycol, povidone, propylene glycol, sodium phosphate dibasic, sodium phosphate monobasic, purified water.

Questions or Comments?

1-844-832-1138 Monday through Friday 9am-5pm

PRINCIPAL DISPLAY PANEL - 15mL Bottle Carton

12 Hour Nasal Spray

Nasal Decongestant

Original

0.5 Fl.OZ (15 mL)



12 HOUR NASAL

oxymetazoline hcl spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69517-613
Route of Administration	NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE - UNII:8VLN5B44ZY)	OXYMETAZOLINE HYDROCHLORIDE	0.05 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69517-613-17	1 in 1 CARTON	01/02/2018	
1		15 mL in 1 BOTTLE, PUMP; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/02/2018	

Labeler - Healthlife of USA (079656178)

Establishment

Name	Address	ID/FEI	Business Operations
Kingston Pharmaceuticals		080386521	manufacture(69517-613)

Revised: 1/2018

Healthlife of USA